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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

061639-0318680

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

10/559,533

Filed

December 2, 2005

First Named Inventor

Tadashi Okiyama

Art Unit

3767

Examiner

Shefali Dilip Patel

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

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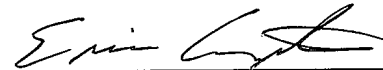
☐ applicant/inventor.

☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☐ attorney or agent of record.  
Registration number \_\_\_\_\_

☒ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 54, 806



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July 21, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## ATTACHMENT SHEETS TO PRE-APPEAL BRIEF REQUEST

### APPEALED REJECTION

In the Final Office Action mailed May 7, 2010 (hereafter “Office Action”):

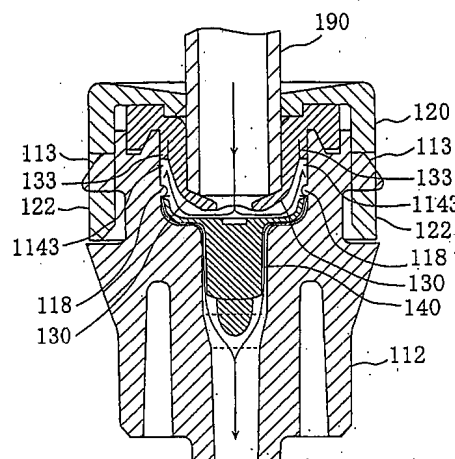
- (i) Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement;
- (ii) Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention;
- (iii) Claims 1-3, 7, 15, 16, 21-23 and 25-27 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Larkin (U.S. Patent No. 5,961,497), in view of Cote (U.S. Patent No. 5,775,671); and
- (iv) Claims 4, 5 and 24 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Larkin and Cote, as applied to claim 2 above, and further in view of Arnett (U.S. Patent No. 5,817,069). Appellant appeals each of these rejections.

### ARGUMENTS

#### **I. Claims 1, 15 and 21 comply with the written description requirement**

The Examiner asserts that “the new recitation that ‘at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate,’ appears to be new matter as the limitation is not stated or described in the specification at all.” Office Action, page 3. Appellant respectfully disagrees.

For instance, Figure 14 of Appellant’s Specification (reproduced below) clearly illustrates the recited subject matter. As illustrated, the arrow with its curved portions specifically shows the flow of the (first) circulating fluid being redirected by the circulating plate 140 to at least a portion of an exposed back surface 1143 of the septum 130.



Moreover, ¶ 70 of Appellant's Specification specifically discloses:

The function of the circulating portion 140 in this embodiment is basically the same as described in the first and the second embodiments. In particular, when the inside of a connector is flush-cleaned with a detergent, ***the circulating portion 140 blocks a flow of the detergent such as heparin or a physiological saline solution that has flown rapidly in the inner cavity 114 to circulate the flow to the septum 130 side and guides the flow to the region 1143 that is formed of the septum 130, the annular rib 133 and the inner wall 115*** (the direction in which the injected detergent flows is shown in FIG. 14). In this region 1143, the gap region 1141, etc. that has been described, for example, in the first embodiment is filled by the function of the annular rib 133.

[emphasis added]<sup>1</sup>.

For *at least* the foregoing reasons, Appellant submits that the Examiner's assertions are without merit, because the claimed subject matter is adequately and amply supported by the Specification. Thus, the rejection of claims 1, 15 and 21 under § 112, ¶ 1, is improper and should be withdrawn.

**II. Claims 1, 15 and 21 clearly point out and distinctly claim the subject matter claimed as the invention**

The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986) (emphasis added).

Appellant submits that one skill in the art having read Appellant's Specification would understand what is meant by "*an exposed back surface of the septum.*" (see, e.g., the discussion above). Moreover, the claims themselves specifically recite that "a portion of an exposed back surface of the septum is in contact with at least a portion of the first circulating fluid." (emphasis added). As such, it is quite clear from the plain language of the claims, what element is exposed to the a portion of the back surface of the septum.

For *at least* the foregoing reasons, Appellant submits that the Examiner's assertions are without merit, as the claims are definite and clear on their face. Thus, the rejection of claims 1, 15 and 21 under § 112, ¶ 2, should be withdrawn.

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<sup>1</sup> See also ¶¶ 43-44.

III. Claims 1-3, 7, 15, 16, 21-23 and 25-27 are patentable over Larkin and/or Cote

Independent claim 1 recites, *inter alia*, the features of:

the circulating member is configured to: circulate the first fluid injected from the inserted tube member to a gap region between the inner wall of the channel tube unit and the septum deformed by the insertion of the tube member ***such that at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate.***

[emphasis added].

The cited portions of Larkin and Cote, whether taken alone or in combination, do not disclose, teach or otherwise render obvious at least the above noted claim features of independent claim 1.

For instance, the Examiner *acknowledges* that “Larkin does not teach a circulating plate,” and that “neither Larkin nor Cote alone teaches a septum and a circulating plate.” [Office Action, pages 10 & 11]. Yet, the Examiner further states that: “It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38(column 5, lines 23-40)” of Cote. [Office Action, pages 4-5].

Appellant submits that the rejection of claim 1 is improper for *at least* the reasons that (i) the Examiner has failed to establish a *prima facie* case of obviousness, (ii) the factual bases underlying the rejection are erroneous, and (iii) the alleged motivation for combining Larkin and Cote is improper.

First, Appellant submits that just because Cote may disclose flushing a port, it does not follow that “an exposed back surface of [a] septum,” is contacted with circulating fluid, as claimed. Indeed, as noted above, the Examiner *acknowledges* that “neither Larkin nor Cote alone teaches a septum and a circulating plate,” let alone any spatial relationship between these two element such that a septum can be flushed. The Examiner, though, asserts that “the circulating plate would be positioned below the septum and the circulating plate allows fluid flow in two opposite directions.” [Office Action, page 11]. Yet, even if this arrangement might be suggested (which Appellant does not concede), the Examiner never mentions that the septum is positioned near the circulating plate so as to be contacted with circulating fluid. Appellant therefore submits that the Examiner has failed to establish a *prima facie* of obviousness

because it fails to address *at least* this feature of claim 1. To be sure "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Second, it appears that an underlying (but unstated) *assumption* of the Examiner's alleged "combination port," is that the seal 70 of Larkin must be placed sufficiently close to the actuator 50 of Cote, if it too, is to be flushed. However, the record is devoid of any evidence to support this assumption. For example, neither Larkin nor Cote make any mention of problems associated with (any portion of) a septum being a surface of stagnation and contamination. Nor has the Examiner provided any evidence, or a basis in fact, to even suggest that contamination on a back surface of the septum had been a problem known in the art, which the alleged combination of Larkin and Cote is to purported to solve. See *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). Indeed, to determine obviousness, the proper inquiry is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) (emphasis added).<sup>2</sup>

That being said, the Examiner has provided no rationale basis, whatsoever, as to why one skilled in the art might consider positioning the seal 70 of Larkin near the actuator 50 of Cote in order to contact "*an exposed back surface of the septum,*" with circulating fluid, as the claims recite.<sup>3</sup> See *C.R. Bard, Inc. v. M3 Sys., Inc.* 157 F.3d 1240, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1988) (a showing of motivation to combine the prior art references is an

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<sup>2</sup> See also *id.* at 82 USPQ2d at 1397 ("One of the ways in which [an appellant's] subject matter can be proved obvious is by noting that ***there existed at the time of invention a known problem*** for which there was an obvious solution encompassed by the patent's claims.") (emphasis added). Moreover, it has been held that "[a] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

<sup>3</sup> As previously pointed out, the combination of Larkin and Cote more likely suggests engaging the lower extending skirt 17 having threads 19 of the connector 10 of Larkin with the inlet section 16 provided with threads 14 of Cote. [See, e.g., Larkin, col. 5, lines 22-24 & Cote, col. 3, lines 40-46 ("The inlet section 16 of the inlet housing component 26 is designed to accept a male Luer fitting 12 by tapering the inner surface 18 of the inlet section."); Fig. 1 (showing male Luer fitting 12 in phantom)]. However, in such a configuration, it does not appear the actuator 50 of Cote (which the Examiner alleges is a circulating plate) would be able to redirect any injected fluid such that any exposed back surface of the seal 70 of Larkin (which the Examiner alleges is a septum) would be contacted with any inject fluid. Indeed, the cited portions of Cote make no mention or suggestion that the actuator 50 redirects fluid up through the male Luer fitting 12 (which would appear necessary to redirect inject fluid towards any seal member that may be connected to an upper portion of the male Luer fitting 12).

“essential evidentiary component of an obviousness holding.”). As discussed, above, the Examiner fails to provide to any factual basis to support this alleged motivation for combining the reference to arrive at the claimed invention. On the other hand, these problems were specifically recognized by the inventors of the present application. [See Appellant’s Specification, ¶¶ 8-11 (discussing problems in prior art with microorganisms growing in stagnation areas 932 of the back surface of septum 920); and ¶¶ 42-44 (discussing one solution to these problems)].

Therefore, absent any proper evidence to support a conclusion of obviousness, Appellant can only reasonably conclude that the Examiner has engaged in impermissible hindsight using Appellant’s own Specification as a roadmap, and submits that the rejection is improper. See *Interconnect Planning Corporation v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (“When prior art references require selective combination by the [examiner] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”) (emphasis added).

Thus, for at least the foregoing reasons, Appellant submits that Larkin and Cote, whether taken alone or combination, fail to disclose, teach or otherwise render obvious each and every feature of amended claim 1. As such, claim 1 is clearly patentable over Larkin and Cote. Claims 15 and 21 recite similar features as claim 1. Therefore, the arguments presented for claim 1 above, similarly apply to claims 15 and 21 as well. Claims 2, 3, 7, 16, 22 and 23 ultimately depend from claims 1, 15 and 21, and are patentable for the same reasons as claims 1, 15 and 21 as well as for their additional recitations. Accordingly, withdrawal of the rejection of claims 1-3, 7, 15, 16, and 21-23 under 35 U.S.C. § 103(a) is requested.

#### **IV. Claims 4, 5, and 24 are patentable over Larkin, Cote, and/or Arnett**

As discussed above, the cited portions of Larkin and Cote do not disclose, teach or otherwise render obvious each and every feature of claim 1. Claims 4, 5 and 24 ultimately depend from claim 1, and are patentable for the same reasons as claim 1 as well as for their additional recitations. Accordingly, withdrawal of the rejection of claims 4, 5 and 24 under 35 U.S.C. § 103(a) is requested.

#### **CONCLUSION**

Therefore, it is respectfully requested that the panel return a decision concurring with Appellant’s position and eliminating the need to file an appeal brief because there are clear legal and/or factual deficiencies in the appealed rejections.